

IN THE CLAIMS

Please amend the claims as follows:

Claims 1-45 (Canceled).

Claim 46 (New): A liquid pharmaceutical composition, comprising:

a follicle stimulating hormone or a variant thereof,

a diluent, and

at least one surfactant selected from the group consisting of PLURONIC F77,

PLURONIC F87, PLURONIC F88 and PLURONIC F68.

Claim 47 (New): The composition according to Claim 46, wherein the follicle stimulating hormone is present in an amount of from 150 IU/ml to 1200 IU/ml.

Claim 48 (New): The composition according to Claim 46, wherein the follicle stimulating hormone is present in an amount of from 300 IU/ml to 900 IU/ml.

Claim 49 (New): The composition according to Claim 46, wherein the follicle stimulating hormone is present in an amount of about 600 IU/ml.

Claim 50 (New): The composition according to Claim 46, wherein the surfactant is PLURONIC F68.

Claim 51 (New): The composition according to Claim 46, wherein the follicle stimulating hormone is human follicle stimulating hormone.

Claim 52 (New): The pharmaceutical composition according to Claim 46, wherein the follicle stimulating hormone is urinary human follicle stimulating hormone.

Claim 53 (New): The composition according to Claim 46, wherein the follicle stimulating hormone is recombinant human follicle stimulating hormone.

Claim 54 (New): The composition according to Claim 46, further comprising at least one bacteriostatic agent selected from the group consisting of phenol and m-cresol.

Claim 55 (New): The composition according to Claim 46, further comprising m-cresol.

Claim 56 (New): The composition according to Claim 46, further comprising m-cresol in an amount of about 0.3% by mass based on the mass of the diluent.

Claim 57 (New): The composition according to Claim 46, further comprising sucrose.

Claim 58 (New): The composition according to Claim 46, further comprising methionine.

Claim 59 (New): The composition according to Claim 46, further comprising a phosphate buffer, wherein the pH of the composition is from 6.0 to 8.0.

Claim 60 (New): The composition according to Claim 46, further comprising a phosphate buffer, wherein the pH of the composition is about 7.0.

Claim 61 (New): The composition according to Claim 46, comprising the diluent, recombinant follicle stimulating hormone, PLURONIC F68, sucrose, methionine, m-cresol, and an aqueous buffer, and wherein the pH of the composition is about 7.0.

Claim 62 (New): The composition according to Claim 61, wherein the recombinant follicle stimulating hormone is present in an amount of about 600 IU/ml, the PLURONIC F68 is present in an amount of about 0.1 mg/ml, the sucrose is present in an amount of about 60 mg/ml, the methionine is present in an amount of about 0.1 mg/ml, the m-cresol is present in an amount of about 3 mg/ml, and the phosphate buffer is present in an amount of about 10 mM in phosphate.

Claim 63 (New): The composition according to Claim 46, wherein the diluent is water for injection.

Claim 64 (New): The composition according to Claim 46, wherein the diluent is at least one of water and a mixture of water with a solvent miscible with water.

Claim 65 (New): A liquid pharmaceutical composition, comprising:
a follicle stimulating hormone or a variant thereof,
a luteinising hormone or a variant thereof,
at least one surfactant selected from the group consisting of PLURONIC F77, PLURONIC F87, PLURONIC F88 and PLURONIC F68, and

a diluent.

Claim 66 (New): The composition according to Claim 65, wherein the follicle stimulating hormone is present in an amount of from 150 IU/ml to 1200 IU/ml.

Claim 67 (New): The composition according to Claim 65, wherein the follicle stimulating hormone is present in an amount of from 300 IU/ml to 900 IU/ml.

Claim 68 (New): The composition according to Claim 65, wherein the follicle stimulating hormone is present in an amount of about 600 IU/ml.

Claim 69 (New): The composition according to Claim 65, wherein the luteinising hormone is present in an amount of from 150 IU/ml to 1200 IU/ml.

Claim 70 (New): The composition according to Claim 65, wherein the luteinising hormone is present in an amount of from 300 IU/ml to 750 IU/ml.

Claim 71 (New): The composition according to Claim 65, wherein the surfactant is PLURONIC F68.

Claim 72 (New): The composition according to Claim 65, wherein the follicle stimulating hormone is human follicle stimulating hormone, the luteinising hormone is human luteinising hormone, or the follicle stimulating hormone is human follicle stimulating hormone and the luteinising hormone is human luteinising hormone.

Claim 73 (New): The pharmaceutical composition according to Claim 65, wherein the follicle stimulating hormone is urinary human follicle stimulating hormone, the luteinising hormone is urinary human luteinising hormone, or the follicle stimulating hormone is urinary human follicle stimulating hormone and the luteinising hormone is urinary human luteinising hormone.

Claim 74 (New): The composition according to Claim 65, wherein the follicle stimulating hormone is recombinant human follicle stimulating hormone, the luteinising hormone is recombinant human luteinising hormone, or the follicle stimulating hormone is recombinant human follicle stimulating hormone and the luteinising hormone is recombinant human luteinising hormone.

Claim 75 (New): The composition according to Claim 65, wherein the follicle stimulating hormone and the luteinising hormone are present in a ratio of from 6:1 to 1:6.

Claim 76 (New): The composition according to Claim 65, wherein the follicle stimulating hormone and the luteinising hormone are present in a ratio of from 4:1 to 1:2.

Claim 77 (New): The composition according to Claim 65, wherein the follicle stimulating hormone and the luteinising hormone are present in a ratio of from 3:1 to 1:1.

Claim 78 (New): The composition according to Claim 65, wherein the follicle stimulating hormone and the luteinising hormone are present in a ratio of from 2:1 to 1:1.

Claim 79 (New): The composition according to Claim 65, further comprising at least one bacteriostatic agent is selected from the group consisting of phenol and m-cresol.

Claim 80 (New): The composition according to Claim 65, further comprising m-cresol.

Claim 81 (New): The composition according to Claim 65, further comprising m-cresol in an amount of about 0.3% by mass based on the mass of the diluent.

Claim 82 (New): The composition according to Claim 65, further comprising sucrose.

Claim 83 (New): The composition according to Claim 65, further comprising methionine.

Claim 84 (New): The composition according to Claim 65, further comprising a phosphate buffer, wherein the pH of the composition is from 6.0 to 8.0.

Claim 85 (New): The composition according to Claim 65, further comprising a phosphate buffer, wherein the pH of the composition is about 7.0.

Claim 86 (New): The composition according to Claim 65, comprising the diluent, recombinant follicle stimulating hormone, PLURONIC F68, sucrose, methionine, m-cresol, and an aqueous buffer, wherein the pH of the composition is about 7.0.

Claim 87 (New): The composition according to Claim 86, wherein the recombinant follicle stimulating hormone is present in an amount of about 600 IU/ml, the PLURONIC F68 is present in an amount of about 0.1 mg/ml, the sucrose is present in an amount of about 60 mg/ml, the methionine is present in an amount of about 0.1 mg/ml, the m-cresol is present in an amount of about 3 mg/ml, and the phosphate buffer is present in an amount of about 10 mM in phosphate.

Claim 88 (New): The composition according to Claim 65, wherein the diluent is water for injection.

Claim 89 (New): The composition according to Claim 65, wherein the diluent is at least one of water and a mixture of water and a solvent miscible with water.

Claim 90 (New): A liquid pharmaceutical composition, comprising:
a diluent,
a luteinising hormone or a variant thereof, and
at least one surfactant selected from the group consisting of PLURONIC F77, PLURONIC F87, PLURONIC F88 and PLURONIC F68.

Claim 91 (New): The composition according to Claim 90, wherein the luteinising hormone is present in an amount of from 150 IU/ml to 1200 IU/ml.

Claim 92 (New): The composition according to Claim 90, wherein the luteinising hormone is present in an amount of from 300 IU/ml to 750 IU/ml.

Claim 93 (New): The composition according to Claim 90, wherein the surfactant is PLURONIC F68.

Claim 94 (New): The composition according to Claim 90, wherein the luteinising hormone is human luteinising hormone.

Claim 95 (New): The composition according to Claim 90, wherein the luteinising hormone is urinary human luteinising hormone.

Claim 96 (New): The composition according to Claim 90, wherein the luteinising hormone is recombinant human luteinising hormone.

Claim 97 (New): The composition according to Claim 90, further comprising at least one bacteriostatic agent selected from the group consisting of phenol and m-cresol.

Claim 98 (New): The composition according to Claim 90, further comprising m-cresol.

Claim 99 (New): The composition according to Claim 90, further comprising m-cresol in an amount of about 0.3% by mass based on the mass of the diluent.

Claim 100 (New): The composition according to Claim 90, further comprising sucrose.

Claim 101 (New): The composition according to Claim 90, further comprising methionine.

Claim 102 (New): The composition according to Claim 90, further comprising a phosphate buffer, wherein the pH of the composition is from 6.0 to 8.0.

Claim 103 (New): The composition according to Claim 90, further comprising a phosphate buffer, wherein the pH of the composition is about 7.0.

Claim 104 (New): The composition according to Claim 90, comprising: the diluent, recombinant luteinising hormone, PLURONIC F68, sucrose, methionine, m-cresol, and an aqueous buffer, and wherein the pH of the composition is about 7.0.

Claim 105 (New): The composition according to Claim 90, wherein the recombinant luteinising hormone is present in an amount of about 600 IU/ml, the PLURONIC F68 is present in an amount of about 0.1 mg/ml, the sucrose is present in an amount of about 60 mg/ml, the methionine is present in an amount of about 0.1 mg/ml, the m-cresol is present in an amount of about 3 mg/ml, and the phosphate buffer is present in an amount of about 10 mM in phosphate.

Claim 106 (New): The composition according to Claim 90, wherein the diluent is water for injection.

Claim 107 (New): The composition according to Claim 90, wherein the diluent is at least of water and a mixture of water and a solvent miscible with water.

Claim 108 (New): A freeze-dried composition, comprising:
a follicle stimulating hormone or a variant thereof, and
at least one surfactant selected from the group consisting of PLURONIC F77,
PLURONIC F87, PLURONIC F88 and PLURONIC F68.

Claim 109 (New): The composition according to Claim 108, wherein the follicle stimulating hormone is present in an amount of from 0.1 to 10 $\mu\text{g}/\text{mg}$ based on the total weight of the formulation.

Claim 110 (New): The composition according to Claim 108, wherein the follicle stimulating hormone is present in an amount of from 0.3 to 5 $\mu\text{g}/\text{mg}$ based on the total weight of the composition.

Claim 111 (New): The composition according to Claim 108, wherein the follicle stimulating hormone is present in an amount of from 0.37 to 2 $\mu\text{g}/\text{mg}$ based on the total weight of the composition.

Claim 112 (New): The composition according to Claim 108, comprising PLURONIC F68.

Claim 113 (New): The composition according to Claim 108, wherein the follicle stimulating hormone is human follicle stimulating hormone.

Claim 114 (New): The composition according to Claim 108, wherein the follicle stimulating hormone is urinary human follicle stimulating hormone.

Claim 115 (New): The composition according to Claim 108, wherein the follicle stimulating hormone is recombinant human follicle stimulating hormone.

Claim 116 (New): The composition according to Claim 108, further comprising at least one bacteriostatic agent selected from the group consisting of phenol and m-cresol.

Claim 117 (New): The composition according to Claim 108, further comprising m-cresol.

Claim 118 (New): The composition according to Claim 108, further comprising m-cresol in an amount of about 0.3% by mass.

Claim 119 (New): The composition according to Claim 108, further comprising sucrose.

Claim 120 (New): The composition according to Claim 108, further comprising methionine.

Claim 121 (New): The composition according to Claim 108, further comprising a phosphate buffer.

Claim 122 (New): The composition according to Claim 108, comprising:
recombinant follicle stimulating hormone, PLURONIC F68, sucrose, methionine, m-cresol,
and a buffer.

Claim 123 (New): A freeze dried composition, comprising:
a luteinising hormone or a variant thereof, and
at least one surfactant selected from the group consisting of PLURONIC F77,
PLURONIC F87, PLURONIC F88 and PLURONIC F68.

Claim 124 (New): The composition according to Claim 123, wherein the luteinising
hormone is present in an amount of from 0.1 to 3 $\mu\text{g}/\text{mg}$ based on the total weight of the
composition.

Claim 125 (New): The composition according to Claim 123, wherein the luteinising
hormone is present in an amount of from 0.1 to 1 $\mu\text{g}/\text{mg}$ based on the total weight of the
composition.

Claim 126 (New): The composition according to Claim 123, wherein the luteinising
hormone is present in an amount of from 0.1 to 0.6 $\mu\text{g}/\text{mg}$ based on the total weight of the
composition.

Claim 127 (New): The composition according to Claim 123, wherein the surfactant is
PLURONIC F68.

Claim 128 (New): The composition according to Claim 123, wherein the luteinising hormone is human luteinising hormone.

Claim 129 (New): The composition according to Claim 123, wherein the luteinising hormone is urinary human luteinising hormone.

Claim 130 (New): The composition according to Claim 123, wherein the luteinising hormone is recombinant human luteinising hormone.

Claim 131 (New): The composition according to Claim 123, further comprising at least one bacteriostatic agent selected from the group consisting of phenol and m-cresol.

Claim 132 (New): The composition according to Claim 123, further comprising m-cresol.

Claim 133 (New): The composition according to Claim 123, further comprising m-cresol in an amount of about 0.3% by mass.

Claim 134 (New): The composition according to Claim 123, further comprising sucrose.

Claim 135 (New): The composition according to Claim 123, further comprising methionine.

Claim 136 (New): The composition according to Claim 123, further comprising a phosphate buffer.

Claim 137 (New): The composition according to Claim 123, comprising recombinant luteinising hormone, PLURONIC F68, sucrose, methionine, m-cresol, and a buffer.

Claim 138 (New): A freeze dried composition, comprising:
a follicle stimulating hormone or a variant thereof,
a luteinising hormone or a variant thereof, and
at least one surfactant selected from the group consisting of PLURONIC F77, PLURONIC F87, PLURONIC F88 and PLURONIC F68.

Claim 139 (New): The composition according to Claim 138, wherein the follicle stimulating hormone is present in an amount of from 0.3 to 5 μ g/mg based on the total weight of the composition.

Claim 140 (New): The composition according to Claim 138, wherein the follicle stimulating hormone is present in an amount of from 0.37 to 2 μ g/mg based on the total weight of the composition.

Claim 141 (New): The composition according to Claim 138, comprising PLURONIC F68.

Claim 142 (New): The composition according to Claim 138, wherein the luteinising hormone is present in an amount of from 0.1 to 1 $\mu\text{g}/\text{mg}$ based on the total weight of the composition.

Claim 143 (New): The composition according to Claim 138, wherein the luteinising hormone is present in an amount of from 0.1 to 0.6 $\mu\text{g}/\text{mg}$ based on the total weight of the composition.

Claim 144 (New): The composition according to Claim 138, wherein the follicle stimulating hormone is human follicle stimulating hormone, the luteinising hormone is human luteinising hormone, or the follicle stimulating hormone is human follicle stimulating hormone and the luteinsing hormone is human luteinising hormone.

Claim 145 (New): The composition according to Claim 138, wherein the follicle stimulating hormone is urinary human follicle stimulating hormone, the luteinising hormone is urinary human luteinising hormone, or the follicle stimulating hormone is urinary human follicle stimulating hormone and the luteinsing hormone is urinary human luteinising hormone.

Claim 146 (New): The composition according to Claim 138, wherein the follicle stimulating hormone is recombinant human follicle stimulating hormone, the luteinising hormone is recombinant human luteinising hormone, or the follicle stimulating hormone is recombinant human follicle stimulating hormone and the luteinsing hormone is recombinant human luteinising hormone.

Claim 147 (New): The composition according to Claim 138, further comprising at least one bacteriostatic agent selected from the group consisting of phenol and m-cresol.

Claim 148 (New): The composition according to Claim 138, wherein the follicle stimulating hormone and the luteinising hormone are present in a ratio of from 6:1 to 1:6.

Claim 149 (New): The composition according to Claim 138, wherein the follicle stimulating hormone and the luteinising hormone are present in a ratio of from 4:1 to 1:2.

Claim 150 (New): The composition according to Claim 138, wherein the follicle stimulating hormone and the luteinising hormone are present in a ratio of from 3:1 to 1:1.

Claim 151 (New): The composition according to Claim 138, wherein the follicle stimulating hormone and the luteinising hormone are present in a ratio of from 2:1 to 1:1.

Claim 152 (New): The composition according to Claim 138, further comprising m-cresol.

Claim 153 (New): The composition according to Claim 138, further comprising m-cresol in an amount of about 0.3% by mass.

Claim 154 (New): The composition according to Claim 138, further comprising sucrose.

Claim 155 (New): The composition according to Claim 138, further comprising methionine.

Claim 156 (New): The composition according to Claim 138, further comprising a phosphate buffer.

Claim 157 (New): The composition according to Claim 138, comprising recombinant follicle stimulating hormone, PLURONIC F68, sucrose, methionine, m-cresol, and a buffer.

Claim 158 (New): The composition according to Claim 138, comprising 32.75 μ g of recombinant follicle stimulating hormone, 9.0 μ g of recombinant luteinising hormone, 15.0 mg of sucrose, 0.052 mg of NaH₂PO₄H₂O, 0.825 mg of Na₂HPO₄ 2 H₂O, 0.5 mg of PLURONIC F68 and 0.05 mg of L-methionine.

Claim 159 (New): The composition according to Claim 138, comprising 65.5 μ g of recombinant follicle stimulating hormone, 18.0 μ g of recombinant luteinising hormone, 30.0 mg of sucrose, 0.104 mg of NaH₂PO₄H₂O, 1.65 mg of Na₂HPO₄ 2 H₂O, 0.10 mg of PLURONIC F68 and 0.10 mg of L-methionine.

Claim 160 (New): A method for manufacturing a pharmaceutical composition, comprising:

mixing a follicle stimulating hormone, at least one surfactant selected from the group consisting of PLURONIC F77, PLURONIC F87, PLURONIC F88 and PLURONIC F68, and a liquid diluent,

to form a solution.

Claim 161 (New): The method according to Claim 160, wherein the surfactant is PLURONIC F68.

Claim 162 (New): The method according to Claim 160, further comprising: mixing at least one bacteriostatic agent selected from the group consisting of phenol and m-cresol, with the follicle stimulating hormone, the surfactant and the liquid diluent.

Claim 163 (New): A method for manufacturing a packaged pharmaceutical composition, comprising:

placing a solution comprising a follicle stimulating hormone, a diluent and at least one surfactant selected from the group consisting of PLURONIC F77, PLURONIC F87, PLURONIC F88 and PLURONIC F68,
into at least one of a vial, ampoule and cartridge.

Claim 164 (New): The method according to Claim 163, wherein the surfactant is PLURONIC F68.

Claim 165 (New): A kit, comprising:
a first container containing a freeze-dried composition comprising a follicle stimulating hormone or a variant thereof, and at least one surfactant selected from the group consisting of PLURONIC F77, PLURONIC F87, PLURONIC F88 and PLURONIC F68, and
a second container containing a diluent for reconstituting the freeze-dried composition.

Claim 166 (New): The kit according to Claim 165, wherein the second container contains an aqueous diluent comprising m-cresol.

Claim 167 (New): A kit, comprising:

a first container containing a freeze-dried composition comprising a luteinising hormone or a variant thereof, and at least one surfactant selected from the group consisting of PLURONIC F77, PLURONIC F87, PLURONIC F88 and PLURONIC F68, and
a second container containing a diluent for reconstituting the freeze-dried composition.

Claim 168 (New): The kit according to Claim 167, wherein the second container contains an aqueous diluent comprising m-cresol.

Claim 169 (New): A kit, comprising:

a first container containing a freeze-dried composition comprising a follicle stimulating hormone or a variant thereof, a luteinising hormone or a variant thereof, and at least one surfactant selected from the group consisting of PLURONIC F77, PLURONIC F87, PLURONIC F88 and PLURONIC F68, and
a second container containing a diluent for reconstituting the freeze-dried composition.

Claim 170 (New): The kit according to Claim 169, wherein the second container contains an aqueous diluent comprising m-cresol.

Claim 171 (New): A method for manufacturing the freeze-dried formulation according to Claim 108, comprising:

mixing the follicle stimulating hormone and the surfactant and subjecting the mixture to lyophilisation.

Claim 172 (New): The method according to Claim 171, wherein the surfactant is PLURONIC F68.

Claim 173 (New): A method for manufacturing a freeze-dried formulation according to Claim 123, comprising:

mixing the luteinising hormone and the surfactant, and subjecting the mixture to lyophilisation.

Claim 174 (New): The method according to Claim 173, wherein the surfactant is PLURONIC F68.

Claim 175 (New): The method for manufacturing the composition according to Claim 138, comprising:

mixing the follicle stimulating hormone, the luteinising hormone, and the surfactant, and subjecting the mixture to lyophilisation.

Claim 176 (New): The method according to Claim 175, wherein the surfactant is PLURONIC F68.

Claim 177 (New): A method for treating infertility, comprising:
administering the composition according to Claim 46 to a human in an effective
amount.

Claim 178 (New): The method according to Claim 177, wherein the follicle
stimulating hormone is administered in an amount of from 150-600 IU.

Claim 179 (New): A method for treating infertility, comprising:
administering the composition according to Claim 65 to a human in an effective
amount.

Claim 180 (New): The method according to Claim 179, wherein one or both of the
follicle stimulating hormone and the luteinising hormone is administered in an amount of
from 150 – 600 IU.

Claim 181 (New): A method for treating infertility, comprising:
administering the composition according to Claim 90 to a human in an effective
amount.

Claim 182 (New): The method according to Claim 181, wherein the luteinising
hormone is administered in an amount of from 150-600 IU.

Claim 183 (New): A method for treating infertility, comprising:
reconstituting the freeze-dried composition according to Claim 108 in a liquid diluent;
and

administering the reconstituted composition to a human in an effective amount.

Claim 184 (New): The method according to Claim 183, wherein the follicle stimulating hormone is administered in an amount of from 150 to 600 IU.

Claim 185 (New): A method for treating infertility, comprising:
reconstituting the freeze-dried composition according to Claim 123 with a liquid diluent; and
administering the reconstituted composition to a human in an effective amount.

Claim 186 (New): The method according to Claim 185, wherein the luteinising hormone is administered in an amount of from 150-600 IU.

Claim 187 (New): A method for treating infertility, comprising:
reconstituting the freeze-dried composition according to Claim 138 with a liquid diluent; and
administering the reconstituted composition to a human in an effective amount.

Claim 188 (New): The method according to Claim 185, wherein one or both of the follicle stimulating hormone and the luteinising hormone is administered in an amount of from 150-600 IU.